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PHARMACISTS ASSOCIATION

THE VOICE OF COMMUNITY PHARMACY

Use of Medication Guides to Distribute Drug Risk Information to Patients
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Colleen Brennan, RPh
Bryan Ziegler, PharmD, MBA

National Community Pharmacists Association

- Founded in 1898 NCPA represents the pharmacist owners, managers, and employees of more than 24,000 independent community pharmacies across the United States

- The nation's independent pharmacies dispense nearly half of the nation's retail prescription medicines

- We share the FDA's interest in making sure that patients utilize medication appropriately and have access to information so they can make informed healthcare decisions

FDA Questions for Pharmacy

- How are pharmacists informed a MedGuide needs to be dispensed?

- How do pharmacists receive MedGuides from manufacturers (e.g., in what format)?

- Challenges in supply…what changes should be made to the Medication Guide program to address these challenges?

- Implementation of electronic distribution (e.g., e-mailed to patients)

- Are MedGuides a valuable tool in counseling patients about drugs with serious risks?

- Should the information be combined or simplified into fewer communication vehicles or do they contain unique information?

- What process improvements could be made to ensure that patients receive appropriate drug risk information at the pharmacy?

- Class MedGuides…advantages/disadvantages

MedGuides in Today's Community Pharmacies

- Required on 60 plus drugs
  - when the NDCs for all distributors' products are tallied, a total of around 9100 require MedGuides….First DataBank current data

- Variable and inconsistent methods to obtain

- Variable readability, length (up to 30 plus pages)

- PDF only

- Patients receive multiple and duplicative types of information (CMI, PPI, PIS)

- Variable methods to inform pharmacist of MedGuide requirement

- Required on new prescription and refills

Medication Guide Distribution

- Inconsistency in how pharmacist is informed to distribute

  - Trade organizations and magazines

  - Computer vendor

  - Drug companies (drug representative)

  - Email notification

  - Colleagues

MedGuides From Manufacturers

- Often manufacturers do not provide pharmacists with MedGuides

- No uniform way to acquire from manufacturers - mechanisms include

  - Tear-off pads with reorder form

  - Attached to the prescription product container (either separate from or buried in prescribing info…but only 1 copy/container)

  - Toll free 800 numbers for pharmacies to order hard copies

Challenges Complying With MedGuide Regulation

- Difficulty incorporating into pharmacy workflow
  - Storage
  - Stopping work flow to download from website
  - Printing on separate printer
- Getting accurate information to distribute….knowing which drugs are required (sheer number of drugs)
- Too much paper for patients
- Pharmacies incur the cost of printing (cost shift to pharmacy from manufacturer)

Electronic Distribution of MedGuides

- Pharmacies would require a good web based program that would interface with the pharmacy management system

- Email is not always practical (retail environment very different)

  - Many patients don't use email

  - Would require an opt-in from patient

  - Increased work flow interruption (beyond normal MedGuide issues due to internet access, changing pharmacy management systems to access patient's email)

- Good or bad depending on where you live

  - Rural internet access a concern

- Electronic format for *manual* printing may cause inconsistent delivery

- If implemented still need availability of *paper* MedGuides

Class MedGuides

- Advantages:

    - Gives an overview about the dangers of all medications in that class and a snapshot of how they work

    - Coalition of manufacturers worked well for NSAIDs and antidepressants giving pharmacy a single point of ordering and consistency in the class MedGuide itself

- Disadvantages:

    - Not all medications are created equal

    - Blanket statements about a class of medications do NOT necessarily mean that it will apply to the one medication from that class that a patient is on and can in some ways, create needless fear in a patient

MedGuide Value as a Patient Counseling Tool

- Difficult to utilize
    - Length and readability
        - Well designed studies on MedGuide effectiveness are needed
        - Reading comprehension of patient versus technical level of the MedGuide
- Patients and caregivers often don't understand them and are sometimes frightened of the "risk" only information
- Patient confusion due to duplicative information (PPI, PIS, CMI)
- MedGuides for refills should be up to pharmacist discretion

NCPA MedGuide Recommendations

- Enforce current FDA MedGuide regulation holding manufacturers accountable for providing:

  - "Medication Guides in sufficient numbers, or the means to produce Medication Guides in sufficient numbers, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product"
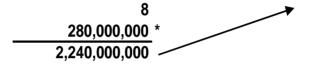
NCPA MedGuide Recommendations

- Revise MedGuide regulation to:

  - Mandate that product manufacturers create electronic, user friendly, product class MedGuides with access on a NDC based database as well as providing *paper* MedGuides

  - Allow incorporation of MedGuides into pharmacy software…caveat: could increase costs of printing because the printers would use a lot more paper

  - Combine branded and generic MedGuides as one document

NCPA MedGuide Recommendations

- Standard message system needed to inform pharmacists

  - Flag drugs – either on container or through pharmacy management system

- Standard ordering system needed for pharmacy

  - FDA ask manufacturers of like MedGuides to form coalition again

  - Allow CMI vendors to provide MedGuides to pharmacy along with CMI

NCPA MedGuide Recommendations

- MedGuides need to be available in *both* hard copy and electronically so that the pharmacies/software vendors can implement the most appropriate version for their workflow/operations

- Formatting standards must be changed so pharmacies can print MedGuides even if they cannot download a PDF file

- Manufacturers *must* bear the direct and indirect costs of distribution &/or printing by pharmacies

MedGuide Printing Cost Estimates

Current Printing Requirements

Average Pages in MedGuide (now)	8	**Total Pages**	2,240,000,000
Total # of Rx requiring MedGuide/yr	280,000,000 *	**Cost/page**	$0.0401 **
Total # of Pages printed/year	2,240,000,000	**Total AnnualCost**	**$89,920,000**

Possible Printing Requirements (if MedGuides 2 pages in length)

Average Pages in MedGuide	2	**Total Pages**	560,000,000
Total # of Rx requiring MedGuide/yr	280,000,000 *	**Cost/page**	$0.0401 **
Total # of Pages printed/year	560,000,000	**Total Annual Cost**	**$22,480,000**

 *Note: Estimated 7% of prescriptions filled require MedGuide.

 **Note: Cost/page calculation includes toner cost + paper cost + administrative cost

***Note: Cost calculations do not factor in any expense for warranty or cost of an additional printer.

MedGuide Printing Cost Estimates

Prices Used in Cost Estimate Calculations

Item	Max Yield (pages)	Price	Source	Cost/page
Lexmark T640 Toner Cartridge	21,000	$352	OfficeDepot.com	$0.0168
Paper (5000 sheets/case)		$50	Staples.com	$0.01
Administrative Cost*				$0.0134
			Estimated Cost/Page	**$0.0401**

Other Prices to Consider (Not Included in Cost Estimate Calculations)

Lexmark T640DN Printer**		$1,100	Staples.com
Warranty		$130-220 Annually	Lexmark

*Administrative cost applied to cover the expense incurred during acquisition, delivery, and storage of supplies used in printing of Medication Guides. Administrative cost is estimated at 50% of cost/page of toner and paper.

**Lexmark is primary brand printer used in retail pharmacy. Customer service representative identified the T640 model as most common used in pharmacies.

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